

REMARKS

This amendment is responsive to the non-final office action mailed July 1, 2005. Independent claims 25, 41, and 54 have been amended as explained herein. Existing dependent claims 39, 40, 43, and 44 have been amended solely to further claim different aspects of the invention and not for reasons related to patentability. New claims 55-59 have been added and depend directly or indirectly from the independent claims. The currently pending claims in this application are 25, 27, 29-32, 34-41, 43, 44, 46-52, and 54-59. Reconsideration and allowance of all pending claims is respectfully requested.

Claims 25, 27, 29-32, 34-41, 43, 44, 46-52, and 54 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,200,347 to Anderson et al. ("Anderson"). The Office Action states that Anderson discloses an intervertebral disc having a cancellous body, two end caps, and cortical struts. These rejections are respectfully traversed in light of the present response.

Independent claims 25, 41, and 54 have been amended in a similar manner to clarify the claimed invention solely for the purpose of expediting prosecution. These claims each are directed to an implant including cortical end caps and struts. As amended, claims 25, 41, and 54 all require an end cap having a recess with a depth less than the height or thickness of the cap. These claims now similarly clarify the bearing surface and struts as follows.

Claim 25 requires the recess having a "wall surface extending along the height of the cap" and a "bearing surface disposed at an angle to the wall surface... so that the strut bears against at least a portion of the bearing surface in the recess." Claim 41 requires "a bearing surface disposed in the recess and oriented at an angle to the height of the end cap" and the strut engaging at least a portion of the bearing surface. Claim 54 requires a first and second end cap each having a recess defining a bearing surface disposed at an angle to the longitudinal axis extending between the top surface and the bottom surface of the end caps, and the strut engaging at least a portion of the first and second bearing surfaces. Anderson does not teach or fairly suggest an implant having a cortical strut engaging a bearing surface as now recited in these claims.

On page 5 of the Office Action, the Examiner states that Anderson discloses that “the bearing surface is the surface created at each hole along the thickness of each cortical cap....” Anderson does not disclose, however, an end cap having a bearing surface that is disposed at an angle to the height, thickness, or longitudinal axis of the end caps and which surface is engaged by a cortical strut as now variously recited in claims 25, 41, and 54. Accordingly, Applicants’ invention as now claimed is distinguishable from Anderson.

Regarding claim 41, the Office Action states that it would have been “an obvious matter of design choice” to modify Anderson “by having a recess that does not extend completely through the end cap because Applicant has not disclosed that by having a recess that does not extend completely through the end cap provides an advantage, is used for a particular purpose, or solves a stated problem.” (Office Action, page 3.)¹ Applicants’ respectfully disagree. Making specific reference to Applicants’ FIG. 16 showing end cap recesses that do not extend completely through the cap, the application as originally filed discloses that an advantage of the novel end cap configuration is to “serve to distribute loadings on the implant.” (See Applicants’ disclosure, page 22, lines 11-12; *see also* FIG. 16.) The purpose and advantage of such an end cap as claimed is not recognized, disclosed, or suggested by Anderson.

Anderson may generally disclose that a spinal implant must withstand mechanical loads (*i.e.*, compression) to prevent collapse of the vertebral disc space during the healing cycle. (See *generally* Anderson, Col. 1, lines 47-57.) However, the solution taught by Anderson is to extend cortical struts completely through holes in the cortical end caps so that the ends of the strut directly contact the adjacent vertebrae. Therefore, compressive loads imposed on the implant by adjacent vertebrae act directly on the ends of the struts (*see* FIG. 11B). This imposes undesirable pinpoint reactionary loads back on the adjacent vertebrae which may cause stress fractures where the struts contact the vertebrae. Moreover, if the compressive loads are not imposed uniformly (*e.g.*, off-center loads, etc.) on the entire end surface of the implant by the adjacent vertebrae, the

¹ Applicants note that the Office Action only fully explains with specificity the obvious rejection with respect to independent claim 41 (*see* top of page 3, first sentence). The entire basis of the obviousness rejection of independent claims 25 and 54 was not fully explained by the Examiner to satisfy a *prima facie* case of obviousness. However, for the sake of expediting prosecution, Applicants have addressed the basis of the Examiner’s rejection for claim 41 as it might relate to claims 25 and 54 which are all believed to be allowable in view of the amendments and remarks contained herein. Should the Examiner disagree, Applicants respectfully reserve the right to receive a full explanation of the basis for the rejection of claims 25 and 54 in view of Anderson.

cortical struts would be unevenly loaded resulting in higher compressive loads in some struts than in others thereby increasing the risk of pinpoint stress-induced vertebrae fractures.

Considering the invention as whole, MPEP 2141.02 (citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983)), Applicants' implant structure now recited in claims 25, 41, and 54 provides more uniform distribution of the compressive loads imposed on the implant by adjacent vertebrae than Anderson. The claimed invention reduces or eliminates pinpoint reactionary loads imparted back to the adjacent vertebrae by precluding direct contact with the struts in contrast to Anderson, thereby reducing the probability of pinpoint vertebrae stress fractures. Also in contrast to Anderson, non-uniform compressive loads imposed on the implant are distributed across the surface area of end cap normal to the load which results in more equal loading of each cortical strut through the claimed recessed bearing surfaces in the end caps which are engaged by the struts. Anderson does not provide such advantages as Applicants' invention as now claimed.

In sum, independent claims 25, 41, and 54 are not obvious in view of Anderson and are believed to be allowable. Likewise, claims 27, 29-32, 34-40, 43, 44, and 46-52, which depend directly or indirectly from independent claims 25, 41, and 54, are believed to be allowable based on the allowability of their respective independent claims and the additional limitations added by these claims which further distinguish over the prior art. MPEP 2143.03 (citing *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988)).

New claims 55-59 depend directly or indirectly from independent claims 25, 41, and 54, and further define different aspects of the invention. These claims are believed to be allowable for at least the same reasons as their respective independent claims discussed herein and the additional limitations added by these claims which further distinguish over the prior art. These new claims are fully supported by Applicants' original disclosure. No new matter has been added.

CONCLUSION

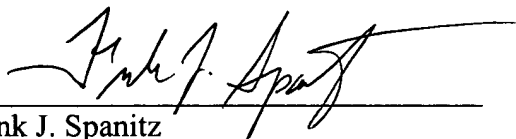
In view of the foregoing, Applicants respectfully request reconsideration and allowance of all pending claims. Should the Examiner disagree with the allowability of any of the claims, the Examiner is respectfully requested to kindly contact Applicants' undersigned representative at 212-309-6375 to resolve any remaining issues.

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

Dated: November 1, 2005

By:


Frank J. Spanitz
Registration No. 47,104

CUSTOMER NO. 009629
MORGAN, LEWIS & BOCKIUS LLP
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
202-739-3000